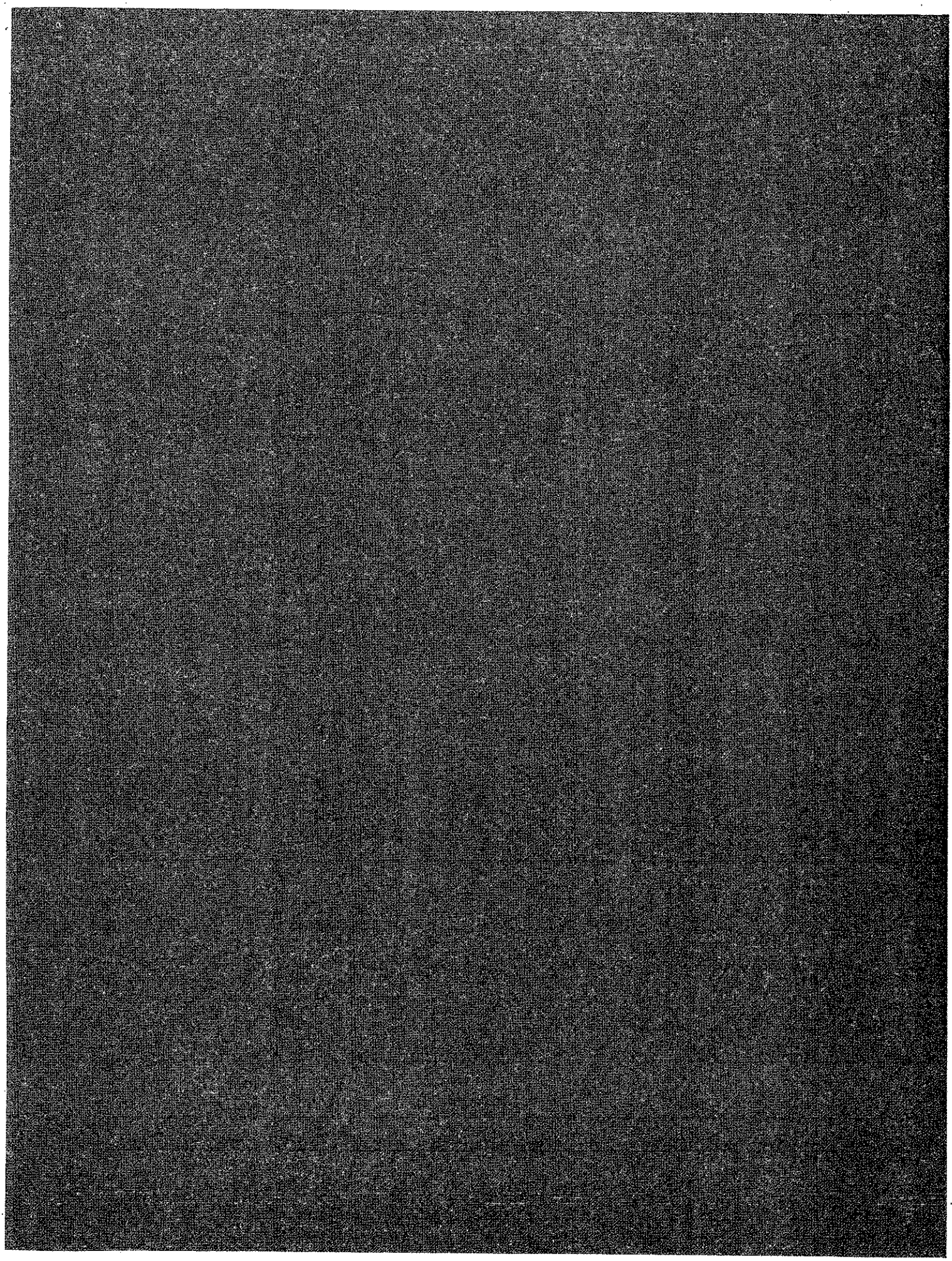
Figures

CHAPTER 9

Medicare payments for outpatient drugs under Part B



CHAPTER 9

Medicare payments for outpatient drugs under Part B

In this chapter

- Coverage and spending
- Issues raised by the current payment system
- Reform efforts
- Lessons from other payers

This chapter looks in depth at one service—Medicare-covered outpatient drugs—for which the Medicare payment method is flawed. Three major problems are that Medicare payments far exceed provider acquisition costs; the system creates incentives for manufacturers to raise their list prices, resulting in increased Medicare payments; and drug administration fees do not reflect the true costs of providing drugs to beneficiaries.

Policymakers are considering how to change the current system. We examined payment methods that other public and private purchasers have developed for physician-administered drugs. We also analyzed the alternatives suggested by the policy community, which include benchmarking methods, payment based on invoice prices, and competitive bidding. Several variants of benchmarking methods are possible, including benchmarking payment amounts to transaction prices that could be audited. Combination approaches based on the competitiveness of the therapeutic drug class are also possible. While each method has advantages and disadvantages, any one of these alternatives would be a significant improvement over the current payment system.

Spending for outpatient drugs covered under Medicare Part B has grown rapidly. Preliminary estimates suggest that expenditures reached $8.5 billion in 2002, an increase of nearly 35 percent over 2001 totals. For the past four years, expenditures have increased annually by more than 20 percent. This growth reflects increased use of the drugs, rising prices, and incremental coverage expansions. Medicare-covered outpatient drugs are mainly used in cancer treatment, dialysis, organ transplantation, and hemophilia. Medicare also covers some outpatient drugs used with durable medical equipment such as infusion pumps and nebulizers.

Medicare pays providers 95 percent of the average wholesale price (AWP) for each covered drug. Despite its name, AWP does not represent the average wholesale price but rather can be thought of as a manufacturer's suggested list price. AWP is not defined in law or regulation and does not have to correspond to any transaction price or average transaction price. A series of studies by the General Accounting Office (GAO) and the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) showed that the current Medicare payment method leads to payments that far exceed providers' costs (GAO 2001b; OIG 2001, 1997, 1996). In some cases, beneficiaries' coinsurance payments alone exceed the price physicians and other providers paid for the drugs.

This chapter describes the current payment method and looks at the potential alternatives being considered by the policy community. We examine the mix of drugs covered by Medicare and analyze trends in spending and provide an overview of the legislative and regulatory history of the payment system, including recent administrative steps taken by CMS. We focus on three problems with the payment system: Medicare payments far exceed provider acquisition costs; the system creates incentives for manufacturers to raise list prices; and high drug prices may, in part, subsidize drug administration fees, which may not reflect the true cost of providing drugs to beneficiaries.

We present some alternatives to reform the Medicare payment system, and analyze how they would affect Medicare payments for covered drugs, how likely they are to affect beneficiary access to needed therapies, what administrative costs they would entail, and how they might affect the operation of the wider pharmaceutical market. While all payment methods have advantages and disadvantages, each option analyzed would be a significant improvement over the current payment system. Most would eliminate manufacturer incentives to raise list prices. Finally, we examine payment methods developed by other public and private payers for physician-administered drugs. These methods provide additional insight into alternatives to the Medicare payment system.

Coverage and spending

Medicare spending for Part B drugs has increased rapidly in recent years, growing by 26 percent in 2001 with corresponding increases in beneficiary obligations for copayments. Beneficiaries who receive these drugs are responsible for paying 20 percent coinsurance after they meet the annual Part B $100 deductible. CMS projects that expenditures totaled $8.5 billion in 2002, an increase of nearly 35 percent.[1] Increased spending is associated with recent coverage expansions. Spending for Part B drugs is highly concentrated. The top 35 drugs accounted for almost 90 percent of drug spending and three specialties—hematology oncology, medical oncology, and urology—accounted for more than half of total billing in 2001.

Which drugs are covered?

In general, Medicare covers drugs administered in physician offices, used as part of durable medical equipment or infusion devices, as well as some oral drugs used following organ transplants. Of the top 20 drugs covered by Medicare in 2001, 7 received Food and Drug Administraton (FDA) approval in 1996 or later.

Drugs currently covered

Under Part B, Medicare covers about 450 outpatient pharmaceutical products and biologics. Spending is highly concentrated among these products. Thirty-five of the covered drugs account for 88 and 95 percent of Medicare drug spending and drug claims volume, respectively. The top 20 drugs covered under Part B are shown in Table 9-1. They accounted for about 77 percent of Part B drug expenditures; nonend-stage renal disease erythropoietin[2] alone accounted for more than 12 percent.

Not generally available through retail pharmacies, these drugs are provided by physicians in their offices or through pharmacy suppliers that provide drugs used with durable medical equipment. They include:

- drugs not self-administered and furnished incidental to a physician's service, such as prostate cancer drugs;
- certain cancer and antinausea drugs available in pill form;
- blood clotting factor;
- immunosuppressive drugs used following organ transplants;
- erythropoietin used to treat anemia in end-stage renal disease patients and cancer patients;
- drugs used as part of durable medical equipment or infusion devices like the albuterol used in nebulizers for asthma and other pulmonary diseases; and

1 Expenditure totals for 2002 are still preliminary. These totals represent carrier paid drugs and do not include intermediary paid drugs including drugs dispensed in outpatient departments of hospitals and freestanding dialysis facilities (see text box, p. 155).

2 The Congress established a separate payment rate for erythropoietin supplied to end-stage renal disease patients in dialysis facilities (see text box, p. 155).

TABLE 9-1

Top 20 drugs covered by Medicare Part B, by share of expenditures, 2001

Drug name	Clinical indications	Type of competition	Date of FDA approval	Percent of Part B drug spending
Non-ESRD erythropoietin	Anemia	Multisource; biological	1989	12.1%
Leuprolide acetate suspension (Lupron)	Prostate cancer	Multisource	1985	10.4
Ipratropium bromide	Asthma and other lung conditions	Generic	1993	7.3
Goserelin acetate implant (Zolodex)	Prostate cancer	Sole source	1989	6.8
Albuterol	Asthma and other lung conditions	Generic	1982	5.5
Paclitaxel injection*	Cancer	Multisource	1992	4.2
Rituximab	Non-Hodgkins lymphoma	Sole source biological	1997	4.2
Pamidronate disodium*	Cancer related	Sole source	1991	3.0
Infliximab	Rheumatoid arthritis, Crohn's disease	Sole source biological	1999	3.1
Docotaxel	Cancer	Sole source	1996	2.6
Carboplatin injection	Ovarian carcinoma	Sole source	1989	2.6
Filgrastin injection	Cancer	Multisource biological	1991	2.5
Irinotecan injection	Cancer	Sole source	1996	2.5
Gemcitabine Hcl	Cancer	Sole source	1996	2.1
IV immune globulin	Immunodeficiency for transplants; HIV	Multisource biological	early 1980s	1.8
Dolasetron mesylate	Cancer related	Sole source	1997	1.8
Hylan G-F 2 injection	Pain from osteoarthritis	Multisource	1997	1.3
Unclassified drugs	N/A	N/A	N/A	1.0
Leucovorin calcium injection	Cancer	Generic	before 1982	1.0
Influenza vaccine	Influenza prevention	Multisource biological	N/A	1.2

Note: ESRD (end-stage renal disease), FDA (Food and Drug Administration), HIV (human immunodeficiency virus), IV (intravenous), N/A (not applicable).
*Now have generic equivalents available.

Source: MedPAC analysis of 2001 Medicare claims data from CMS and unpublished FDA data.

- osteoporosis drugs provided to certain beneficiaries by home health agencies.

Physician-billed drugs account for the largest share of program spending. In 2001, physician claims accounted for more than 80 percent of total Medicare expenditures for outpatient drugs. This category includes many brand name drugs and biologicals for which no competition exists, and that tend to be more expensive than generic drugs (see text box, p. 153).

Billing is concentrated in certain specialties (Figure 9-1, p. 152). Most claims are submitted by oncologists. Three specialties—hematology oncology, medical oncology, and urology—submitted claims for 58 percent of total billing for Part B-covered drugs. Primary care physicians submitted claims for an additional 6.4 percent of covered drugs. For some specialties, payments for Part B drugs represent a large portion of total Medicare payments. In 2001, 72 percent of all Medicare payments to hematology oncologists and medical oncologists were for Part B drugs. Similarly, 64, 43, and 31 percent of Medicare payments to hematologists, urologists, and rheumatologists, respectively, were for covered drugs.[3]

Pharmacy-supplier billed drugs account for the largest volume of drug claims: Two inhalation therapy drugs, albuterol and ipratropium bromide, accounted for 88 percent of prescriptions filled by pharmacy suppliers for home administration in 1999. This category tends to contain more lower cost drugs with generic equivalents.

Medicare also pays for some outpatient drugs and biologicals provided in immunization centers and independent laboratories.

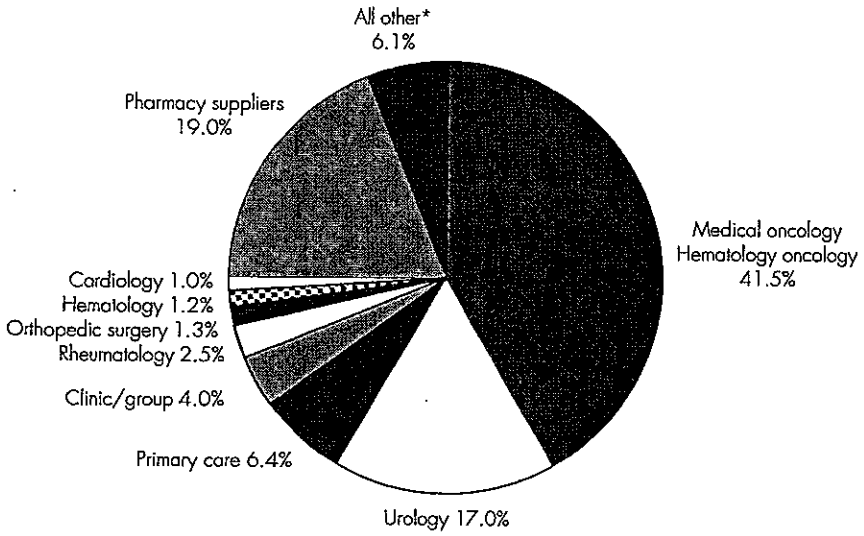
How coverage has expanded

Coverage policies for Part B-covered drugs have been a continuing subject of Congressional interest and controversy. The Congress has gradually increased the quantity, type, and duration of drugs covered to address additional beneficiary needs. Although the Congress mandates the categories of drugs that Medicare covers, decisions by CMS and local carriers determine the specific drug products eligible for reimbursement. There can be significant differences in coverage for specific drugs by regional carriers.

Legislation expanded drug coverage under Part B three times in the past decade. Each legislative change has led to calls for further expansions:

3 MedPAC analysis of 2001 Medicare claims data from CMS.

FIGURE 9-1 **Medicare drug spending, by physician specialties and other providers, 2001**



* No other provider had expenditures equal to at least 1 percent of total Medicare drug spending.

Source: MedPAC analysis of Medicare claims data, 2001.

- Since 1993, Medicare has covered cancer drugs administered through oral dosages if injectable forms were already available, but not otherwise. This policy left gaps that led advocates to call for the coverage of all cancer drugs. For example, a new class of cancer drugs that disrupt the growth of cancer cells without damaging surrounding tissues is being developed. The first such drug, Gleevec, approved for treatment of chronic myelogenous leukemia, came on the market last year. Because this breakthrough drug has never had an injectable form, it is not covered by Medicare.

- A provision in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) expanded the class of drugs eligible for coverage from those that are not self-administered to those not *usually* self-administered. This policy has led to calls for broader coverage of self-injectable drugs. In May 2002, a CMS program memorandum clarified the coverage rules: Drugs delivered by intramuscular injection are covered, but drugs delivered through subcutaneous injections are not. Thus, Medicare will cover Avonex, one drug that treats multiple sclerosis, because it is delivered through intramuscular injection, but does not cover any other drugs for this condition. Carriers can make exceptions based upon a number of factors including frequency of administration, but not based on the capabilities of the individual patient. Legislation in both Houses of Congress would increase Medicare coverage for self-injectables.

- A previous expansion mandated coverage of immunosuppressives for beneficiaries receiving organ transplants. Coverage was limited to three years even though patients must continue taking these medications for the rest of their lives. A provision in BIPA removed the three year time limit for coverage. In the 107th Congress, legislation was introduced to require continuing coverage of immunosuppressives for Medicare beneficiaries, regardless of whether they received transplants while enrolled in Medicare.

Several other bills requiring incremental expansions in Part B drug coverage are before the Congress.

What is Medicare's payment policy?

Medicare has used different methods to reimburse providers and suppliers for outpatient drugs over time. Before 1992, Medicare carriers generally paid for drugs based on physicians' estimated costs as measured by the AWP. In 1992, Medicare formalized this policy and it fixed payments for covered outpatient drugs at 100 percent of AWP.

AWP and Medicare payments

Despite its name, AWP does not represent the average wholesale price. AWP can be thought of as the published suggested wholesale price of a drug or a manufacturer's suggested list price. It does not have to correspond to any transaction price or average transaction price. Actual transaction prices often reflect substantial discounts. Every drug has its own AWP. Because information about the actual prices manufacturers charge their customers is proprietary, AWPs are one of the few publicly available sources of drug prices.

AWP has never been defined in statute or regulation. Individual AWPs are compiled and reported in compendia like the Red Book and First Databank, largely on the basis of information supplied by manufacturers. Because there is no official calculation method, CMS potentially can use alternate sources of information like market surveys to establish new AWPs for setting Medicare payment rates. These rates could be tied to actual transaction prices.

Glossary of terms

Biologic: a product derived from living material—human, plant, animal, or microorganism—applicable to the prevention, treatment, or cure of diseases or injuries of humans. A company patents the *production process* for manufacturing a biologic rather than the product itself.

Biotechnology: a set of tools that employ living organisms (or parts of organisms) to make or modify products, improve plants or animals, or develop microorganisms for specific uses. Modern biotechnology includes the use of recombinant DNA and monoclonal antibodies.

- **Recombinant DNA** (rDNA or *in vitro recombination*): molecules constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.
- **Monoclonal antibody:** laboratory-produced substances that can locate and bind to cancer cells wherever they are in the body. Many monoclonal antibodies are used in cancer detection or therapy. Monoclonal antibodies can be used alone or to deliver drugs, toxins, or radioactive material directly to a tumor.

Drug: any chemical compound used in the prevention, diagnosis, treatment, or cure of disease, for the relief of pain, or to control or improve any physiological or pathological disorder in humans or animals. Drugs produced by more than one manufacturer are called generic or multiple source. Drugs produced by one manufacturer are called single source drugs.

- **Generic drug:** identical, or bioequivalent, to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.
- **Multiple source (multisource) drug:** marketed or sold by two or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two or more different brand names. This category includes both generic and brand name drugs.
- **Single source drug:** marketed or sold by only one manufacturer or labeler under one brand name.

Inhalation therapies: a group of respiratory treatments designed to help restore or improve breathing function in patients with a variety of diseases, conditions, or injuries.

Infusion therapies: treatments involving the administration of medications, nutrients, or other solutions into the bloodstream, under the skin, into the digestive system, or into the membranes surrounding the spinal cord.

Injection methods: Three injection methods are intramuscular, intravenous, and subcutaneous.

- **Intramuscular injection:** an injection given into a muscle of the body. CMS defines drugs delivered by this method as not usually self-administered by the patient.
- **Intravenous injection:** a process of slowly injecting fluids and drugs into a blood vessel.
- **Subcutaneous injection:** an injection beneath the skin.

Radiopharmaceutical: a pharmaceutical, biologic, or drug that contains a radioactive entity.

Therapeutic class: a group of drugs similar in chemical structure, pharmaceutical effect, and/or clinical use. There are many different ways of classifying therapeutic classes. ■

From 1992 until 1997, Medicare calculated reimbursement for covered outpatient drugs on the basis of 100 percent of the published AWPs. A continuing series of investigations by the OIG (OIG 1997, 1996) demonstrated that this method resulted in Medicare paying far more than other public purchasers for these drugs. The OIG compared the rates Medicare paid with the prices advertised in catalogues published by drug wholesalers and group purchasing organizations, the sources most physicians and pharmacy suppliers use to purchase their stock. The drugs were widely available to purchasers at prices well below AWP. After considerable debate, the Balanced Budget Act of 1997 (BBA) set payment rates for Medicare covered single source drugs and biologics at 95 percent of AWP.[4]

Current Medicare payment rates are:

- for brand name drugs produced by a single manufacturer (referred to as single-source drugs), 95 percent of AWP.

4 The President's fiscal year 1998 budget contained an alternate proposal for AWP reform.

- for drugs for which there are two or more competing brand name products (referred to as multisource drugs) or generic equivalents available, 95 percent of the lower of (a) the median AWP of all generic forms of the drug or (b) the lowest brand-name product AWP.

Coding issues

The AWP payment method has resulted in reimbursement inconsistencies among carriers.[5] The OIG found wide variation in prices paid by local carriers for covered drugs even though all payments were based on the same formula. Much of the difficulty stems from differences in how physician-administered drugs are coded by Medicare as well as many private payers. Medicare relies on Healthcare Common Procedure Coding System (HCPCS) codes to identify drugs for payment. Under this classification scheme, most covered drugs are assigned J-codes. For drugs administered outside of physician offices, other public and private payers use a coding system based on national drug codes (NDCs) maintained by the FDA. Every drug sold in the United States has a unique NDC that provides information on the chemical molecule, the drug manufacturer, dosage, dosage form, and package size. AWPs are attached to each NDC. To determine drug AWPs for purposes of Medicare payment, carriers must convert HCPCS codes into corresponding NDC codes.

While some HCPCS codes correspond to only one NDC, others can represent as many as ten. Even when a HCPCS code identifies a single drug, NDC codes might differ depending upon the size of the package from which the drug was dispensed. Carriers had to choose the AWP from a single NDC code or compute an AWP from several corresponding NDC codes. Each carrier could make a different decision. Carriers also differed in frequency of updating AWPs. In a recent study, the OIG found that carriers' payment amounts for a single HCPCS code differed by more than 10 percent.

CMS recently addressed this problem by the establishment of a single drug pricer (SDP) for drugs and biologicals covered under Medicare Part B. The section on CMS efforts to reform the payment system discusses inherent reasonableness and the SDP policy.

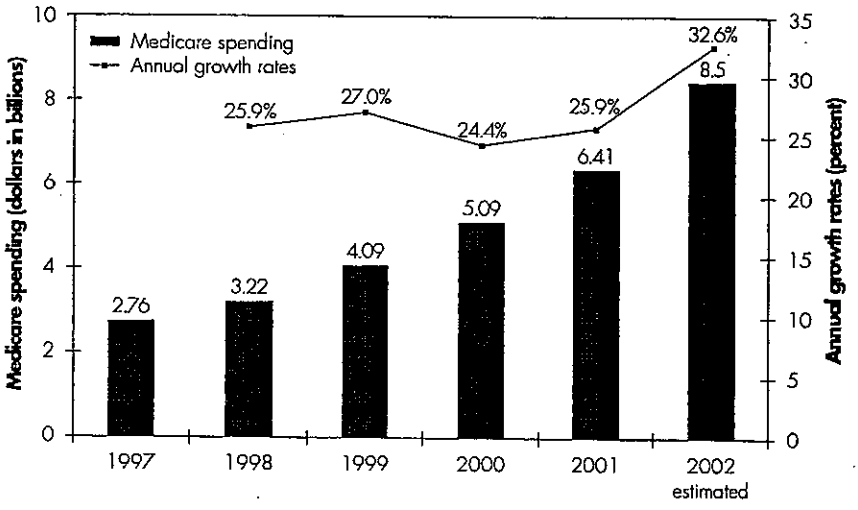
Why has spending increased?

Total spending for Medicare Part B-covered drugs (that is, program spending and beneficiary cost sharing) rose from about $700 million to $4 billion from 1992 to 1999. Between 1999 and 2000 alone, spending increased an additional $1 billion. Total spending increased by 26 percent, or nearly $1.5 billion, in 2001 to reach $6.4 billion (Figure 9-2). Expenditures for Part B drugs now equal about 3 percent of total Medicare spending (see text box at right). Preliminary estimates suggest that expenditures rose to $8.5 billion in 2002, an increase of nearly 35 percent.

The primary reason for growth in this sector is the increased volume of drugs used and the substitution of newer and more expensive medications for older therapies. More people are living with serious chronic diseases and new treatments for managing these diseases are being developed. Of the top 20 drugs covered by Medicare in 2001, 7 received FDA approval in 1996 or later (Table 9-1, p. 151). In addition, the types of new drugs under development are driving up costs. Manufacturers of breakthrough technologies for these diseases have some incentive to produce injectables rather than oral solids because they have lower drug development costs, greater potency per dose, and higher efficacy rates (Ransom 2002). Also, Medicare coverage for outpatient drugs, other than those supplied in conjunction with certain items of durable medical equipment (DME), is generally limited to those requiring physician administration.

The most significant factor driving spending growth is the emergence of an increasing number of drugs produced through the use of biotechnology. More than 80 such products have received FDA approval and over 350 additional products targeting more than 200 diseases are

FIGURE 9-2 **Medicare spending and annual growth rates for Part B drugs**



Source: Unpublished CMS data.

5 Carriers are private organizations, usually insurance companies, that serve as the government's fiscal intermediary for items and services provided under Medicare Part B.